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10/554,711

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

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1636

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/554,711 | Applicant(s) MCDONALD, JOHN F | |
| | Examiner Jennifer Dunston | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-42 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to a method of determining an expression pattern of one or more families of transposable elements in a sample, comprising determining expression of one or more families of transposable elements.

Group II, claim(s) 16-30, drawn to a method of determining a methylation pattern of one or more families of transposable elements in a sample, comprising determining methylation of one or more families of transposable elements.

Group III, claim(s) 31-42, drawn to a method of determining a chromatin status pattern of one or more families of transposable elements in a sample comprising determining chromatin status of one or more families of transposable elements.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-III do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is determining an expression pattern of one or more families of transposable elements in a sample which is shown by Depil et al (Leukemia, Vol. 16, No. 2, pages 254-259, February 2002) to lack novelty or inventive step. Depil et al teach determining expression of HERV-K transposable elements in a sample (e.g., page 255, Qualitative RT-PCR and Quantitative RT-PCR; page 256, Northern blotting; Figure 2; Table 1). Therefore the technical feature does not make a contribution over the prior art and does not constitute a special technical feature.

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Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention of Group I. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(A) assigning the expression pattern to the type of cancerous cell; and

(B) determining the expression of one or more families of transposable elements in a sample obtained from a subject after administration of an anti-cancer therapeutic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species (A), claims 2-12 and claims 14-15 (in part).

Species (B), claims 13 and claims 14-15 (in part).

The following claim(s) are generic: claim 1.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The species do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking the species is determining an expression pattern of one or more families of transposable elements in a sample which is shown by Depil et al (Leukemia, Vol. 16, No. 2, pages 254-259, February 2002) to lack novelty or inventive step. Depil et al teach determining expression of HERV-K transposable elements in a sample (e.g., page 255, Qualitative RT-PCR and Quantitative RT-PCR; page 256, Northern blotting; Figure 2; Table 1). Therefore the technical feature linking the species does not make a contribution over the prior art and does not constitute a special technical feature.

This application contains claims directed to more than one species of the generic invention of Group II. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (A) assigning the methylation pattern to the type of cancerous cell; and
- (B) determining the methylation of one or more families of transposable elements in a sample obtained from a subject after administration of an anti-cancer therapeutic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species (A), claims 17-23 and claims 25-30 (in part).

Species (B), claims 24 and claims 25-30 (in part).

The following claim(s) are generic: claim 16.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The species do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking the species is determining an expression pattern of one or more families of transposable elements in a sample which is shown by Florl et al (British Journal of Cancer, Vol. 80, No. 9, pages 1312-1321, 1999) to lack novelty or inventive step. Florl et al teach determining a methylation pattern of LINE-1 and HERV-K transposable elements in a sample (e.g., Figures 1-3). Therefore the technical feature linking the species does not make a contribution over the prior art and does not constitute a special technical feature.

This application contains claims directed to more than one species of the generic invention of Group III. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(A) assigning the chromatin status pattern to the type of cancerous cell; and

(B) determining the chromatin status of one or more families of transposable elements in a sample obtained from a subject after administration of an anti-cancer therapeutic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

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the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species (A), claims 32-38 and claims 40-42 (in part).

Species (B), claims 39 and claims 40-42 (in part).

The following claim(s) are generic: claim 31.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The species do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking the species is determining an expression pattern of one or more families of transposable elements in a sample which is shown by Voelker et al (Genetics, Vol. 126, pages 1071-1082, 1990) to lack novelty or inventive step. Voelker et al teach determining a DNase I hypersensitive regions (chromatin status pattern) of transposable elements in a sample (e.g., Figure 3). Therefore the technical feature linking the species does not make a contribution over the prior art and does not constitute a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is (571) 272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston
Examiner
Art Unit 1636

/JD/

/Daniel M Sullivan/
Primary Examiner, Art Unit 1636